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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,743	02/26/2002	Anabella Villalobos	PC10802A	2304

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EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 03/14/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,743	VILLALOBOS, ANABELLA	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 13-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 7, submitted December 9, 2002.

Applicant's election with traverse of invention group I, claims 1-12, and the species of particular compounds as GABAA and NRPA components in Paper No. 7 is acknowledged. The traversal is on the ground(s) that search of all the inventions herein is not an undue burden. This is not found persuasive because the search of invention group II is not required for the search of group I. Further, the search is not limited to patent literature.

The requirement is still deemed proper and is therefore made FINAL.

The claims have been examined insofar as they read on elected species.

Claim Objections

1. Claims 8 is objected to because of the following informalities: The employment of parenthetical expression, e.g., ("the X carbocyclic group" or "the Y carbocyclic group"), in claims is considered informal. Appropriate correction is required.

Double Patenting Rejections

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1617

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, and 14 of U.S. Patent No. 6,410,550 in view of Albaugh et al. (WO 99/10347, IDS). '550 claims compounds herein employed as NRPA, and pharmaceutical composition comprising the same for treating anxiety, or cognitive disorders. See particularly claim 8, 12 and 14.

4. '550 does not expressly claim that the composition additionally comprising GABAA.

5. However, Albaugh et al. (WO 99/10347, IDS) teaches that GABAA such as those employed herein are known to be useful for treating anxiety or cogitative disorder. See, particularly, the abstract, claim 24.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a pharmaceutical composition comprising both the NRPA and GABAA agents herein employed.

A person of ordinary skill in the art would have been motivated to make a pharmaceutical composition comprising both the NRPA and GABAA agents herein employed because both agents are known to be useful for treating anxiety or cognitive disorders. It is prima facie obvious to combine two agents each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the

Art Unit: 1617

claimed invention which is a combination of two agents known to be useful for treating anxiety or cognitive disorders sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069.

Claim Rejections 35 U.S.C. 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3-7 recites the broad recitation, "less than -5%; greater than 5%" in claim 3; "of 200 nM" in claim 4, "greater than 5%" in claim 5, "of 200 nM" in claim 6, and "of 100 nM" in claim 7, and the claim also recites "less than -10%" and "greater

Art Unit: 1617

than 10%" in claim 3, "less than 150 nM" in claim 4, "greater than 10%" in claim 5, "less than 150 nM" in claim 6, and "less than 30 nM" in claim 7, which is the narrower statement of the range/limitation.

9. Claim 8 recites "from 3-7 members" in lines 10-11 at page 37, it is not clear what the "members" represent.

10. The term "lower" in claim 8, lines 28-29, is a relative term which renders the claim indefinite. The term "lower" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The claim is indefinite as to the length of the alkyl defined therein.

11. Claim 8 recites "where each alkyl may be optionally substituted..." it is unclear as to whether the limitation "substituted.." is actually in the claims.

Claim Rejections 35 U.S.C. 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albaugh et al. (WO 99/10347, IDS) and Coe et al. (WO 99/35131, IDS).

14. Albaugh et al. (WO 99/10347, IDS) teaches that GABAA such as those employed herein are known to be useful for treating anxiety or cognitive disorder. See, particularly, the abstract, the claims, especially, claim 24. Coe et al. teaches the compounds herein employed as NRPA,

Art Unit: 1617

and pharmaceutical composition comprising the same for treating anxiety, or cognitive disorders.

See particularly, the abstract, examples 26, and the claims.

15. The cited references do not expressly teach a pharmaceutical composition comprising both GABAA and NRPA.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a pharmaceutical composition comprising both the NRPA and GABAA agents herein employed.

A person of ordinary skill in the art would have been motivated to make a pharmaceutical composition comprising both the NRPA and GABAA agents herein employed because both agents are known to be useful for treating anxiety or cognitive disorders. It is prima facie obvious to combine two agents each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two agents known to be useful for treating anxiety or cognitive disorders sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Art Unit: 1617

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner

SHENGJUN WANG
PATENT EXAMINER

Shengjun Wang

March 12, 2003